K101075



# 510(k) Summary

**Introduction**

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

**Submitter name, address, contact**

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250

JUN 11 2010

Contact Person: Sarah Baumann
Phone: 317-521-3952
Fax: 317-521-2324
Email: sarah.baumann@roche.com

Secondary Contact: Stephanie Greeman
Phone: 317-521-2458
Fax: 317-521-2324
Email: stephanie.greeman@roche.com

Date Prepared: April 16, 2010

**Device Name**

Proprietary name: Elecsys® Insulin CalCheck 5
Common name: Insulin CalCheck 5
Classification name: Single (specified) analyte controls (assayed and unassayed)

**Predicate device**

The Elecsys Insulin CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys HCG+β CalCheck 5 (K092168).

**Device Description**

The Elecsys Insulin CalCheck 5 is a lyophilized product consisting of recombinant human insulin in bovine serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

**Intended use**

The Elecsys Insulin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Insulin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

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# 510(k) Summary, Continued

**Comparison Table**

The table below compares Elecsys Insulin CalCheck 5 with the predicate device, Elecsys HCG+β Calcheck 5 (K092168).

| Characteristic | Elecsys HCG+β CalCheck 5 (K092168) | Elecsys Insulin CalCheck 5 |
|---|---|---|
| Intended Use | The Elecsys HCG+β CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys HCG+β reagent on the indicated Elecsys and **cobas e** immunoassay analyzers. | The Elecsys Insulin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Insulin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers. |
| Matrix | Human serum matrix | Bovine serum matrix |
| Levels | Five | Same |
| Format | Lyophilized | Same |
| Handling instructions | Reconstitute the contents of each vial with exactly 1.0 mL distilled or deionized water.<br><br>Allow the bottle to stand closed for 15 minutes. Mix gently by inversion to ensure homogeneity. | Same |
| Stability | Unopened:<br>• Store at 2-8°C until expiration date<br><br>Reconstituted:<br>• 20 – 25°C : 4 hrs | Same |

**Performance Characteristics**

The Elecsys Insulin CalCheck 5 was evaluated for value assignment and stability.

**Conclusion**

The data demonstrate that the performance of the Elecsys Insulin CalCheck 5 is substantially equivalent to that of the predicate device, Elecsys HCG+β CalCheck 5 (K092168).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Roche Diagnostics Corp.
c/o Ms. Sarah Baumann
Regulatory Affairs Consultant
9115 Hague Road, PO Box 50410
Indianapolis, IN 46250-0416

JUN 11 2010

Re: k101075
Trade Name: Elecsys® Insulin CalCheck 5
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed).
Regulatory Class: Class I, reserved
Product Codes: JJX
Dated: April 16, 2010
Received: April 19, 2010

Dear Ms. Baumann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use Form

510(k) Number (if known): K101075

Device Name: Elecsys Insulin CalCheck 5

Indications for Use: The Elecsys Insulin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Insulin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101075